

REMARKS

Claims 7-32 are presently pending in this application. Claims 30-32 have been withdrawn from consideration by the Office pursuant to an Election of Species requirement. Examined claims 7-29 stand variously rejected under 35 U.S.C. §§ 112 and 102.

Claim 7 has been amended herein to indicate that the claimed polynucleotide encodes a polypeptide comprising one of the 8 amino acid sequences explicitly recited in the claim. As in the previously presented claims, the fragments necessarily include octapeptides comprising residue 72 of SEQ ID NO:1 in which the wild-type Ala has been replaced with a an Arg residue. Withdrawn claims 30-32 have been similarly amended. Applicants note that claims 7 and 30 are now duplicative due to identity as between SEQ ID NO:1 and SEQ ID NO:2. Thus, claims 7-32 are pending as shown above.

The amendments are made solely to advance prosecution and are not intended as an admission that the Examiner's position was correct. No new matter has been added as a result of these amendments and entry thereof is respectfully requested.

Election of Species

Applicants reiterate that their traversal of the election of species requirement was based on the fact that it would not be unduly burdensome to search all sequences together. In addition, Applicants noted that the Office had not properly delineated the differences between the allegedly distinct species encompassed by these claims and, accordingly, Applicants could not elect a single species. In any event, it is to be understood that upon allowance of a generic claim, Applicants will be entitled to consideration of claims to the additional species.

Drawings

The Examiner requests clarification as to the status of FIG. 12. The Examiner had previously objected to Figure 12 as allegedly containing new matter not described in the original specification and reiterates this objection in paragraph 3 of the outstanding Office Action.

Applicants addressed this issue in detail in their Response After Final, filed concurrently with the RCE filed November 18, 2002. This response, reproduced below, establishes that FIG. 12 does **not** include new matter and should be entered.

The proscription against the introduction of new matter in a patent application (35 U.S.C. 132 and 251) serves to prevent an applicant from adding information that goes beyond the subject matter originally filed. See, e.g., *In re Rasmussen*, 650 F.2d 1212, 1214, 211 USPQ 323, 326 (CCPA 1981) and MPEP § 2163.06. Further, the claims as filed in the original specification are

part of the disclosure. Therefore, if an application as originally filed contains a claim disclosing material not found in the remainder of the specification, the applicant may amend the specification to include the claimed subject matter. *See, e.g., In re Benno*, 768 F.2d 1340, 226 USPQ 683 (Fed. Cir. 1985).

In the pending case, the alleged "added" information does not in any way go beyond the subject matter originally filed. With regard to both Figure 12 and the sequences presented in the claims, Applicants note that the originally filed application specifically references Domenighini et al. (1995) for its disclosure of porcine and human sequences containing an Alanine at residue 72 (where the 72 refers to the position of the "correct" sequence presented in Figures 1 and 2 of Domenighini and added as Figure 12 herein). In addition, the originally filed claims also specifically referred to the Ala-72 residue of Domenighini as found in the amended claims and specification. Similarly, Domenighini also includes sequences presented in Figure 12 and as SEQ ID NOs:2-4 of the Sequence Listing. Thus, there is nothing in Figure 12 that goes beyond the originally filed subject matter and, accordingly, new matter has not been added.

Applicants also disagree with the Examiner's contention that Domenighini was not properly incorporated by reference into the application. (See, pages 3-4 of the Final Office Action). The proper legal standard for determining if a reference is "properly" cited is not determining whether the words "incorporation by reference" appear next to the reference. Rather, the proper test involves examining the application for the context in which the reference is cited. *See, e.g., MPEP 608.01(p) and In re Hawkins*, 179 USPQ 157 (CCPA 1973). Thus, mere reference, for example by listing of a number of references without pointing to specific teachings in these references or by simply using the words "continuation in part," is not a "proper" incorporation of these references. *See, In re de Seversky*, 177 USPQ 144 (CCPA 1973). In contrast, citing a reference for specific teachings in a specific context is not a "mere" reference. Indeed, the Federal Circuit has recently held that mere mention of the *title* of a journal article could be sufficient to describe claims in view of the understanding of the skilled artisan. *Atmel Corp. v. Information Storage Devices Inc.*, 53 USPQ2d 1225, 1231 (Fed. Cir. 1999).

Here, Applicants properly referenced Domenighini et al. in the specification on page 5. Moreover, this identification of Domenighini is entirely for specific teachings regarding the sequence of various LT-A proteins and, additionally, for alignment of these various sequences showing the position of amino acids relative to the wild-type Ala-72 in the porcine LT-A protein. Thus, Applicants have properly amended the specification to include sequences from these references and from sequences publically available at the time of filing.

Even assuming, for the sake of argument only, that Domenighini was not properly referenced, it is also well settled that applicants must be afforded an opportunity to correct incorporate material deemed essential into their specification. *See, e.g.,* M.P.E.P. 608.01(p)(I)(A)(2). Indeed, in *Hawkins*, the CCPA made clear that subsequent amendment of the specification to recite the teachings of the reference will properly cure any defect in disclosure alleged by the Office and that editing the application by inserting that which was previously properly referenced does not raise new matter issues. *In re Hawkins*, 179 USPQ at 161. Here, the Examiner maintains that the teachings in Domenighini are essential and that they were not properly incorporated by reference. By inserting the sequences of Domenighini into the specification, Applicants have entirely cured the alleged defect. In this regard, Applicants also note that the sequences of Domenighini and those added to the specification were publically available at the time of filing. (See, *e.g.*, previously submitted GenBank entry).

Finally, Applicants also traverse the Examiner's assertion that the sequence presented as SEQ ID NO:1 differs from that presented in Domenighini or from the sequences that were publically available at the time of filing. Applicants can find no difference as between SEQ ID NO:1 (as claimed) and the "correct" sequences presented in Figures 1 and 2 of Domenighini. Further, even if certain amino acids were different as between Domenighini and Figure 12, it is well known that sequencing errors are a common problem in molecular biology. See, *e.g.*, Peter Richterich, Estimation of Errors in 'Raw' DNA Sequences: A Validation Study, 8 Genome Research 251-59 (1998). Any discrepancies in sequence between Domenighini and Figure 12 fall under the category of "minor errors" that can readily be corrected. Indeed, prior to the filing of the present application, the sequence of LT-A was updated in January, 1996. (See, attached GenBank entry). Further, the GenBank entry also indicates that this is not an instance in which a deposit was made after the filing date of the application. Rather, the GenBank entry indicates that the starting wild-type LT-A sequences was available at the time of filing.

Thus, Applicants submit that the amendments to the claims and to the specification do not constitute the addition of new matter. Nonetheless, if the Examiner prefers, Applicants would be willing to incorporate the sequence directly into the specification following the reference to Domenighini.

35 U.S.C. § 112, Second Paragraph

Claims 7-29 are rejected under 35 U.S.C. § 112, second paragraph as allegedly indefinite. (Office Action, paragraph 4). In support of this rejection, the Examiner requests clarification as to how an octapeptide can have a residue at position 72; how a short peptide can be "numbered relative

to SEQ ID NO:1; and how position 72 can be an arginine instead of alanine residue. (Office Action, paragraph 4).

Applicants submit that that the foregoing amendments to claim 7 obviate this rejection. In particular, structural characteristics of the claimed fragments are now specified by explicit recitation of 8 octapeptides, one of which must be part of the claimed fragments. In view of the foregoing amendments, Applicants request withdrawal of this rejection.

35 U.S.C. § 102(b)/103

Claim 7-29 remain rejected under 35 U.S.C. § 103 as allegedly obvious over EP 145486. In addition, claims 7-29 remain rejected under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent No. 5,770,203 (hereinafter "Burnette"). (Office Action, paragraphs 5 and 6).

Neither EP 145486 nor Burnette teach or suggest a polynucleotide that encodes an amino acid comprising one of the octapeptides recited the claims, namely SLRSAHL**R**, LRSAHLRG, RSAHLRGQ, SAHLRGQS, AHLRGQSI, HLRGQSIL, LRGQSILS or RGQSILSG. Rather, both EP 145486 and Burnette disclose only polynucleotides encoding peptides having an Ala residue at the Arg residue (shown in bold) of the claimed molecules. Further, there is no suggestion in EP 145486 to mutate the sequence shown in FIGs. 1 or 2 to arrive at the precisely claimed molecules. (See, Table 1 of EP 145486 suggesting only mutations to FIGS. 1 and 2 that do not affect this residue).

Thus, the cited references do not describe, demonstrate or suggest the claimed molecules -- all of which encode a polypeptide comprising one of the octapeptides set forth in claim 7. Withdrawal of these rejections is respectfully requested.


CONCLUSION

In view of the foregoing, Applicant submits that the claims are now in condition for allowance and requests early notification to that effect. Please direct all further communications regarding this application to:

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Respectfully submitted,

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